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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: **March 22, 2011**

To: **Board Members**

Subject: **Agenda Item VI – Legislation and Regulation Committee**

Discussion and Possible Action to Initiate a Rulemaking to Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels

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On January 1, 2011, the board's requirements for a patient-centered prescription drug container label took effect.

During the rulemaking process to adopt the prescription drug labeling requirements, the board decided to establish requirement(s) that consumers be notified of the availability of oral language interpretive services in pharmacies and of 12-point font, as specified in the regulation.

The board considered possible regulatory language for this at its July 2010 Board meeting, and thereafter directed staff to develop new language. The board voted at that time to move the existing consumer notices from 16 CCR § 1702. to a new section that would also include any notice(s) regarding language interpretive services and larger font sizes.

At the October 2010 Board Meeting, the board continued its discussion of the possible regulation text and made modifications to subdivisions (a) and (b) of the draft text.

At the February Board Meeting, the board generally discussed the requirements but did not modify the language (a copy of the draft minutes from this segment of the meeting is at the back of this section).

Provided on the following pages is a copy of the possible regulation language discussed at the October 2010 meeting, showing changes made at that meeting.

At this meeting, the board will have substantial time to refine the requirement for the consolidated notice to consumers. If the board completes its work, the board can direct that staff release the draft proposal for the required 45-day initial notice period.

Draft Text for discussion at the February 2011 Board Meeting

This text reflects changes made at the October 2010 Board Meeting, along with staff recommendations. Line numbering is provided for reference.

Delete 16 CCR § 1707.2, subds. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer~~s~~, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the ~~such~~ approval ~~to a committee or the Executive Officer.~~ As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

You may ask this pharmacy to use 12-point font on prescription drug labels.

Oral language services are available to you at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available**,** the pharmacy will work with you to ensure that you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by *a* prescription drug consumer~~s~~, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text repeated in English and in each of the languages for which interpretive services are available, printed in an least an 18-point boldface type in a color that sharply contrasts with the background color of the notice, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This text shall be repeated in at least fourteen (14) languages, to include all of the non-English languages now or hereafter identified by the Medi-Cal Managed Care Division, Department of Health Care Services, for translation of vital documents, as well as any other primary languages for groups of ten thousand (10,000) or more limited-English-proficient persons in California.

The pharmacy may post this notice in paper form or on a video screen meeting the requirements of subdivision (a) if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a cardstock flyer or handout clearly visible from and kept within easy reach of each counter in the

pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer/handout shall be at least 8 1/2 inches by 11 inches, shall be printed on durable cardstock, and may be laminated.

1707.2 Notice to Consumers and Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: of his or her right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's 129 discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for selfmonitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

~~(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~"NOTICE TO CONSUMERS"~~

~~At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone. Ask your pharmacist if a lower-cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.~~

~~Before taking any prescription medicine, talk to your pharmacist; be sure you know:~~

~~What is the name of the medicine and what does it do?~~

~~How and when do I take it – and for how long? What if I miss a dose?~~

~~What are the possible side effects and what should I do if they occur?~~

~~Will the new medicine work safely with other medicines and herbal supplements I am taking?~~

~~What foods, drinks or activities should I avoid while taking this medicine?~~

~~Ask your pharmacist if you have additional questions.~~

~~(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~Know your rights under California law concerning medicine and devices prescribed to you.~~

~~You have the right to receive medicine and devices legally prescribed to you, unless:~~

~~1. The medicine or device is not in stock in the pharmacy,~~

~~2. The pharmacist, based upon his or her professional judgment determines providing the item:~~

- ~~is against the law,~~
- ~~could cause a harmful drug interaction, or~~
- ~~could have a harmful effect on your health~~

~~This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.~~

~~The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe. If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.~~

~~Any questions? Ask the pharmacist!~~

Authority cited: Sections 4005 and 4122, Business and Professions Code.
Reference: Sections 733, 4005 and 4122, Business and Professions Code.

EXCERPT: Minutes of the February 1, 2011 Board Meeting
Part 2 - Regulations

4. Discussion and Possible Action to Initiate a Rulemaking to Add Title 16 Section 1707.6 and to Amend Section 1702 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels

Dr. Schell provided that on June 10, 2010, the board adopted its regulation at 16 CCR § 1707.5 to establish requirements for a patient-centered prescription drug container label. He indicated that the regulation was approved by the Office of Administrative Law on November 17, 2010, and became effective on January 1, 2011. Dr. Schell stated that the regulation requires a pharmacy to provide a consumer with 12-point font for certain components of a prescription label, if requested, and also requires a pharmacy to provide oral interpretive services.

Dr. Schell provided that during the rulemaking process to adopt the prescription drug labeling requirements, it was suggested that the board establish requirement(s) that consumers be notified of the availability of oral language interpretive services and of a 12-point font, as specified in the regulation.

Dr. Schell provided that the board considered possible regulatory language at its July 2010 Board meeting, and thereafter directed staff to develop new language. He stated that the board voted at that time to move the existing consumer notices from 16 CCR § 1702 to a new section that would include any notice(s) regarding language interpretive services and larger font sizes. Dr. Schell indicated that at the October 2010 Board Meeting, the board continued its discussion of the possible regulation text and made modifications to subdivisions (a) and (b) of the draft text.

Ms. Herold suggested that the board view a notice to consumers video produced by Ralphs. She stated that the video includes a vignette of the notice content, rather than just the notice text. Ms. Herold provided that the video does conform to the regulation.

The board viewed the video.

Dr. Castellblanch expressed concern regarding use of the terms “12-point font” and “oral language services.” He discussed that 60 seconds may not be a sufficient amount of time to display the text of the notice on a video screen. Dr. Castellblanch provided that these issues can be discussed as the process moves forward.

Mr. Room provided that the issues discussed by Dr. Castellblanch were all changes made as a result to the board’s previous discussion.

Mr. Brooks discussed the limited space available in pharmacies to post notices. He encouraged the board to consider this limited space when drafting the notice requirement.

Ms. Veale provided that Ralphs has indicated that the video screen option would work as a solution to the limited space option.

Mr. Brooks cautioned the board from being too prescriptive with regards to the requirement that the text of the notice be displayed on the screen for a minimum of 60 seconds.

The board discussed whether the 60 second specification is an appropriate and adequate timeframe. It was clarified that 60 seconds is a minimum as the board has previously discussed that a shorter period of time would not be sufficient.

Ms. Veale discussed that the language regarding a pharmacist's ability to refuse to fill a prescription for ethical, moral or religious reasons has been removed.

Mr. Room provided that there was previous discussion that the consumer is more concerned with their right to have the pharmacy help them obtain their prescription and less concerned regarding the right of the pharmacist to decline to fill the prescription. He clarified that this latter language was removed in the effort to condense and decrease the length of the notice language.

Ms. Veale stated that at the October 2010 Board Meeting counsel was directed to draft alternative language for subdivision (b) regarding conscientious objection to fill a prescription.

Mr. Room apologized that this language was not prepared. He indicated that he will draft the requested language.

Ms. Herold discussed the timeline for the rulemaking process. She indicated that if noticed today, the earliest the process would be completed is a year to a year and a half from now.

Mr. Brooks suggested that the board break up the process and evaluate the language to identify portions that are acceptable and other portions that need to be addressed.

President Weisser suggested that this item be referred back to the committee for discussion at a focused meeting before being brought back to the board.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed the limited space available in pharmacies and stated that the video screen alternative would be a solution so long as the requirements are not too prescriptive. He commended the notice video produced by

Ralphs. Dr. Gray encouraged the board to focus on how best to convey the notice information instead of how long the information should be displayed.

Dr. Gray discussed the language services requirement and provided that the board needs to provide pharmacies with references to aid in identifying languages for this requirement.

Dr. Gray expressed concern regarding language that states that the pharmacy will work with the consumer to ensure that they get their medicine or device in a timely manner. He stated that this is only a statutory legal requirement related to the ability of a pharmacist to conscientiously object. Dr. Gray discussed that the language is beyond what is required by the statute and is beyond the ability of some pharmacies to comply.

Mr. Room provided that he does not agree that the language is beyond the requirements of the statute. He reviewed that current section 1707.2 states that if the pharmacy is unable to fill a prescription, the consumer is entitled to have the prescription returned or transferred to another nearby pharmacy and specifies that a pharmacy will have in place a procedure to help consumers get items that the pharmacy does not have in stock.

Dr. Kajioka discussed that requiring a pharmacy to find another source to provide the consumer with an out of stock medication is time consuming and hinders the care of other patients.

The board further discussed the issue of assisting the consumer with obtaining medication that is out of stock and the requirements of Business and Professions Code section 733. The board was advised by its legal counsel that the requirements of Sections 1707.2 and 733 should apply to a pharmacy regardless of whether a particular item is regularly stocked or not.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), provided that NACDS members have expressed concern regarding subdivision (a) with respect to the 60 second minimum and 5 minute time lapse. She stated that these requirements stifle creativity and should be removed.

Ms. Staples encouraged the board to take as much time as necessary to address subdivision (c) regarding language services. She suggested that most non-English speaking consumers will bring an English speaking caregiver to assist them; and, as such, the point to your language option would suffice. Ms. Staples encouraged the board to require that the text be repeated in the top five languages in the state instead of 14 as drafted in the language.

Ms. Staples asked for clarification regarding the standards or thresholds for languages identified by the Medi-Cal Managed Care Division. She also asked how pharmacies are to identify languages with 10,000 or more limited-English-proficient persons in California as specified in lines 52-54 of the draft language.

Ms. Staples suggested that the board consider handouts as an alternative to the notice posting requirement and discouraged prescriptive requirements (such as cardstock and size) in this area.

Mr. Room provided that based on previous discussions of the board at the July and October 2010 Board Meetings, there was a consensus that the notice provision could be reduced to a handout and that 14 languages would be the maximum number of languages required. He clarified that the language regarding languages with 10,000 or more Limited-English-proficient persons originated in a bill by Senator Corbett.

Dr. Schell requested that Ms. Staples provide any additional comments in writing.

Ms. Shellans discussed that the draft language is not ready for board action as more clarification should be added to subdivision (c). She stated that this can be accomplished by either listing each required language or by incorporating by reference a document that identifies the specific languages that are required.

Mr. Room recommended that the board incorporate an external reference.

Shirley Wheat encouraged that the committee meet prior to the next board meeting. She asked whether non-committee members can provide a recommendation to the committee chair.

Ms. Shellans provided that the board can convene a working group or refer this matter back to the committee to make a recommendation. She advised that non-committee members can submit comments to the executive officer to provide to the committee in the committee meeting materials.

Dr. Castellblanch provided comment on the regulation process and encouraged the board to move expeditiously. He discussed that the required languages should be based on established criteria and not on an arbitrary number.

Ms. Herold provided that in addition to discussion of the notice language at the next committee meeting, the committee will also need to offer recommendations to the board on legislation. She advised the committee that this will need to be a full day meeting and should be scheduled for the beginning of April 2011 in order to have the workload completed prior to the May 2011 Board Meeting.

It was the consensus of the board to refer this item back to the Legislation and Regulation Committee.